House Bill 885 GEORGIA LEGISLATION

By: Representatives Peake of the 141st, Watson of the 166th, Channell of the 120th, Kaiser of the 59th, Gravley of the 67th, and others

A BILL TO BE ENTITLED
AN ACT

To amend Article 5 of Chapter 34 of Title 43 of the Official Code of Georgia Annotated, relating to the use of cannabis for treatment of cancer and glaucoma, so as to provide for continuing research into the benefits of medical cannabis to treat certain conditions; to provide for a short title; to provide for legislative findings and intent; to provide for the continuation of the Controlled Substances Therapeutic Research Program; to provide for selection of academic medical centers to conduct the research; to provide for expansion of the review board and its duties; to establish the responsibilities of academic medical centers; to provide for the testing, storing, and dispensing by the Georgia Drugs and Narcotics Agency; to provide for immunity; to provide for related matters; to repeal conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.

WHEREAS, the General Assembly finds and declares that clinical research has shown certain benefits arising from the utilization of medical cannabis and, most recently, significant benefits of a particular strain delivered orally for the treatment of seizure disorders among children.

WHEREAS, nothing in this legislation should be construed as encouraging or sanctioning the recreational use of cannabis, nor is this legislation to be construed as any intent of the General Assembly to be moving in the direction of the legalization of recreational cannabis.

SECTION 2.

Article 5 of Chapter 34 of Title 43 of the Official Code of Georgia Annotated, relating to the use of cannabis for treatment of cancer and glaucoma, is amended by revising the article as follows:

"ARTICLE 5

43-34-120.

This article shall be known and may be cited as the ~~'Controlled Substances Therapeutic Research~~ 'Haleigh's Hope Act.'

43-34-121.

(a) The General Assembly finds and declares that ~~the potential medicinal value of marijuana has received insufficient study due to a lack of financial incentives for the undertaking of appropriate research by private drug manufacturing concerns. Individual physicians cannot feasibly utilize marijuana in clinical trials because of federal governmental controls which involve expensive, time-consuming approval and monitoring procedures~~ this legislation's purpose is the compassionate potentially life-saving use of medical cannabis and is not intended to sanction, encourage, or otherwise be construed as a movement toward the legalization of recreational cannabis. Clinical research performed over the past decades continues to show benefits arising from medical cannabis. Presently there are in excess of one million United States medical cannabis patients and an increasing number of physicians are recommending the therapeutic use of cannabis to their patients in accordance with their respective state law. New extracts and compounds have been developed demonstrating that cannabidiol, one of the most prevalent nonpsychoactive cannabinoids, has significant health and wellness benefits as shown by recent publication of the positive treatment of certain seizure disorders afflicting children.

(b) The General Assembly further finds and declares that ~~limited~~ continuing studies throughout the nation indicate that ~~marijuana~~ cannabis and certain of its derivatives possess valuable and, in some cases, unique therapeutic properties, including the ability to treat cancer, as well as relieve nausea and vomiting which routinely accompany chemotherapy and irradiation used to treat cancer patients. ~~Marijuana~~ Cannabis also may be effective in treating, as well as reducing intraocular pressure in glaucoma patients ~~who do not respond well~~ in adjunct to conventional medications. Cannabis derivatives have recently shown to be effective in the treatment of seizure disorders among other conditions and diseases.

(c) The General Assembly further finds and declares that, in enabling ~~individual physicians and their~~ patients to participate in a state-sponsored program for the investigational use of ~~marijuana~~ cannabis and its derivatives, ~~qualified physicians and surgeons throughout the state~~ academic medical centers will be able to study the benefits of the drug in a controlled clinical setting, and additional knowledge will be gained with respect to dosage and effects.

(d) It is the intent of the General Assembly in enacting this article to permit research into the therapeutic and treatment applications of ~~marijuana~~ cannabis and its derivatives in cancer, ~~and~~ glaucoma, and seizure disorder patients. This would allow qualified ~~physicians~~ academic medical centers approved by the Patient Qualification Review Board created by Code Section 43-34-124 to ~~provide~~ authorize use of the drug on a compassionate basis to seriously ill persons suffering from cancer, as well as the severe side effects of chemotherapy or radiation treatment, ~~and~~ to persons suffering from glaucoma ~~who are not responding to conventional treatment~~, and to persons suffering from seizure disorders, which persons would otherwise have no lawful access to it. It is the further intent of the General Assembly to facilitate clinical trials of ~~marijuana~~ cannabis and its derivatives, particularly with respect to persons suffering from cancer, ~~and~~ glaucoma, and seizure disorders who would be benefited by use of the drug.

(e) This article is limited to clinical trials and research into therapeutic applications of ~~marijuana~~ cannabis only for use in treating glaucoma, ~~and~~ in treating cancer and the side effects of chemotherapeutic agents and radiation, and utilizing medical cannabis for the treatment of seizure disorders and should not be construed as either encouraging or sanctioning the social use of cannabis ~~marijuana. Nothing in this article shall be construed to encourage the use of marijuana in lieu of or in conjunction with other accepted medical treatment, but only as an adjunct to such accepted medical treatment~~.

43-34-122.

As used in this article, the term:

(1) 'Academic medical center' means a research hospital that operates a medical residency program for physicians and conducts research that involves human subjects.

~~(1)~~(2) 'Board' means the Georgia Composite Medical Board.

~~(2)~~(3) 'Cannabis' ~~'Marijuana'~~ means ~~marijuana~~ cannabis or tetrahydrocannabinol, as defined or listed in Article 2 of Chapter 13 of Title 16.

(4) 'Medical cannabis for the treatment of seizure disorders' means cannabis extracts and compounds of cannabis, including, but not limited to, those strains used to manufacture cannabidiol, a nonpsychoactive cannabinoid, that is delivered to the patient in a nonsmoking delivery system whether it be in the form of liquid, pill, vaporization, or injection or other delivery method that does not include smoking.

~~(3)~~(5) 'Physician' means a person licensed to practice medicine pursuant to Article 2 of this chapter.

~~(4)~~(6) 'Program' means the Controlled Substances Therapeutic Research Program established pursuant to Code Section 43-34-123.

~~(5)~~(7) 'Review board' means the Patient Qualification Review Board established pursuant to Code Section 43-34-124.

43-34-123.

(a) There is established under the Georgia Composite Medical Board the Controlled Substances Therapeutic Research Program, which shall be administered by the board. Under the program, the board shall act as a sponsor of state-wide investigational studies, utilizing ~~as drug investigators individual physicians who elect~~ academic medical centers selected by the board to participate in accordance with the guidelines and protocols developed by the board. Such guidelines and protocols shall be designed to ensure that stringent security and record-keeping requirements for research drugs are met and that participants in the program meet those research standards necessary to establish empirical bases for the evaluation of ~~marijuana~~ cannabis as a medically recognized therapeutic substance. The board shall promulgate such rules and regulations as it deems necessary or advisable to administer the program. In promulgating such guidelines, protocols, rules, and regulations, the board ~~shall~~ may take into consideration those pertinent rules and regulations promulgated by the ~~Federal~~ United States Drug Enforcement ~~Agency~~ Administration, the Food and Drug Administration, and the National Institute on Drug Abuse.

(b) The program shall be limited to patients who are certified to the board by a ~~physician~~ selected academic medical center as being:

(1) Cancer patients involved in a life-threatening situation in which treatment by chemotherapy or radiology has produced severe side effects; ~~or~~

(2) Glaucoma patients who are not responding to conventional controlled substances; or

(3) Seizure disorder patients.

(c) No patient may be admitted to the program without full disclosure by the ~~physician~~ academic medical center of the experimental nature of the program and of the possible risks and side effects of the proposed treatment.

(d) The cost of any blood test required by the ~~federal~~ Food and Drug Administration prior to entrance into the program shall be paid by the patient or through the program, donated study funds, or funding seeking entrance into the program.

(e) Only the following persons shall have access to the names and other identifying characteristics of patients in the program for whom ~~marijuana~~ cannabis has been prescribed under this article:

(1) The board;

(2) The review board created by Code Section 43-34-124;

(3) The Attorney General or his or her designee;

(4) Any person directly connected with the program who has a legitimate need for the information; ~~and~~

(5) Any federal agency having responsibility for the program;

(6) Any academic medical center operating a program under this article; and

(7) Any patient program participant's attending physician.

43-34-124.

(a) The board shall appoint the Patient Qualification Review Board. Each member of the review board shall be approved for such membership by a majority vote of the board and shall serve at the pleasure of the board. The review board shall be composed of:

(1) A board certified physician in ophthalmology;

(2) A board certified physician in surgery;

(3) A board certified physician in internal medicine and medical oncology;

(4) A board certified physician in psychiatry;

(5) A board certified physician in radiology; ~~and~~

(6) A pharmacist licensed under Chapter 4 of Title 26, relating to pharmacists, pharmacy, and drugs;

(7) A board certified physician in pediatric neurology;

(8) A board certified physician in pain management; and

(9) A board certified pediatric epitologist.

(b) The review board shall elect from its members a chairperson and a vice chairperson. The review board shall hold regular meetings at least once every 60 days and shall meet at such additional times as shall be called by the chairperson of the review board or the chairperson of the board. Each member of the review board shall receive for services for each day's attendance upon meetings of such board the same amount authorized by law for members of the General Assembly for attendance upon meetings of the General Assembly.

(c) The board shall adopt such rules and regulations as it deems necessary for the performance of the duties of the review board.

(d) The review board: ~~shall review all patient applicants for the program and their physicians and shall certify those qualified for participation in the program. The review board shall additionally certify pharmacies which are licensed by the state and which are otherwise qualified and certify physicians regarding the distribution of marijuana pursuant to Code Section 43-34-125. Meetings of the review board to certify patients, physicians, or pharmacies shall not be open to the public, as otherwise required by Chapter 14 of Title 50~~

(1) Shall review, evaluate, and rate applications for medical cannabis use programs submitted by academic medical centers based on the procedures and guidelines established by the board;

(2) Shall develop request applications for programs;

(3) Shall approve or deny applications for programs, approve or deny applications for renewal of such programs, and monitor and oversee programs approved for operation under this article;

(4) May rescind approval of a program if the board finds that the program is not in compliance with the conditions of approval established by the board;

(5) Shall set application fees and renewal fees that cover its expenses in reviewing and approving applications and providing oversight to programs; and

(6) May accept any gifts, donations, contributions, grants, bequests of funds or property, or other funds.

43-34-125.

(a) ~~The board~~ An academic medical center operating a program approved under this article shall apply to contract with the National Institute on Drug Abuse for receipt of ~~marijuana~~ cannabis pursuant to this article and pursuant to regulations promulgated by the National Institute on Drug Abuse, the Food and Drug Administration, and the ~~Federal~~ United States Drug Enforcement ~~Agency~~ Administration or obtain such cannabis, cannabinoid, or any other derivative, compound, or substantially similar products from any available source.

(b) ~~The board shall cause marijuana approved for use in the program to be transferred to a certified pharmacy, licensed by the state, for distribution to the certified patient by a licensed pharmacist upon a written order for research medication of the certified physician, pursuant to this article. Any reasonable costs incurred by the board in obtaining or testing marijuana shall be charged to participating physicians who may seek reimbursement from their research subjects utilizing the marijuana.~~ Upon receipt of the research cannabis, its extracts, compounds, or derivatives, or any other substantially similar product, the academic medical center shall test the specifications of such product. Upon completion of its testing of such product, the academic medical center shall notify the Georgia Drugs and Narcotics Agency.

(c) Upon notification by the academic medical center, the Georgia Drugs and Narcotics Agency shall take possession of the research product acquired under subsection (a) of this Code section and retain such product until such time as the product shall be distributed by the agency to the academic medical center.

(d) The Georgia Drugs and Narcotics Agency shall establish rules and regulations for the storing and distributing of the research cannabis.

43-34-126.

~~Patient participants in the program are immune from state prosecution for possession of marijuana as authorized by this article and under the program established in this article. A person authorized under this program shall not possess an amount of marijuana in excess of the amount prescribed under the authority of this article. The amount prescribed shall be maintained in the container in which it was placed at the time the prescription was filled. Physician, pharmacy, and pharmacist participants in the program are immune from state prosecution for possession, distribution, and any other use of marijuana, which use is authorized such persons by this article. Any such possession, distribution, or other use not authorized by this article shall be enforced and punished as provided in Chapter 13 of Title 16, relating to controlled substances and dangerous drugs, and Chapter 4 of Title 26, relating to pharmacists and pharmacies.~~

(a) The academic medical center operating a program approved under this article shall report annually or more frequently as the board deems necessary to the board in a manner specified by the board that includes the following:

(1) The number of patients served through the program and their county of residence;

(2) The conditions treated under the program; and

(3) Any outcome data on the results of the treatment through the program.

(b) An academic medical center operating a program approved under this article shall apply annually to the board for renewal of approval of the program, in accordance with procedures established by the board.

(c) An academic medical center operating a program under this article is subject to inspection by the board to ensure that the program is operating according to the conditions of approval established by the board.

43-34-127.

Any of the following persons acting in accordance with the provisions of this article shall not be subject to arrest, prosecution, or any civil or administrative penalty, including a civil penalty or disciplinary action by a professional licensing board, or be denied any right or privilege, for the medical use, prescription, administration, manufacture, or distribution of medical cannabis:

(1) A patient enrolled in a program approved under this article who is in possession of an amount of cannabis authorized under the program or such patient's caregiver, parent, or guardian; or

(2) An academic medical center, an employee of an academic medical center, or any other person associated with the operation of a program approved under this article for activities conducted in accordance with the program approved under this article.

43-34-128.

A state employee is eligible for reimbursement for incurred counsel fees under Code Section 45-12-26 in the event of a federal criminal investigation or prosecution solely related to the employee's good faith discharge of public responsibilities under this article."

SECTION 3.

All laws and parts of laws in conflict with this Act are repealed.